K092649

Appendix I Updated 510(k) Summary

FEB - 4 2010

Premarket Notification, 510(k) for Elecsys proBNP II STAT Assay		
Immunoassay Comparison		
Feature	**Predicate Device: Elecsys proBNP II Assay (K072437) (18 Minute)**	**Elecsys proBNP II STAT Assay**
General Assay Features		
Intended Use/ Indications for Use	Immunoassay for the *in vitro* quantitative determination of N-terminal pro-brain natriuretic peptide in human serum and plasma. The Elecsys proBNP II assay is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure. The test may also serve as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.	Same, except: The assay name is changed: ...The Elecsys proBNP II STAT assay is used as an aid in the diagnosis... Elecsys instruments are removed: The electrochemiluminescence immunoassay "ECLIA" is intended for use on the **cobas e 601** immunoassay analyzer.
Assay Protocol	Sandwich assay	Same
Detection Protocol	Electrochemiluminescent Immunoassay	Same
Application	18 Minute	STAT (9 Minute)
Instrument Platform	Roche Elecsys 2010/**cobas e** 411 and MODULAR ANALYTICS E170/**cobas e** 601	**cobas e** 601
Sample Volume	15 µL	Same

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Premarket Notification, 510(k) for Elecsys proBNP II STAT Assay, Continued

Immunoassay Comparison		
Feature	**Predicate Device: Elecsys proBNP II Assay (K072437) (18 Minute)**	**Elecsys proBNP II STAT Assay**
General Assay Features		
Sample Type	Human serum and plasma treated with K_2-EDTA, K_3-EDTA, lithium heparin and Na-heparin plasma.	Same
Reagents	The proBNP II Assay is a sandwich immunoassay with two antibodies directed towards epitopes within the N-terminal portion of the proBNP molecule. The capture antibody is biotinylated to react with streptavidin-coated microparticles. The signal antibody is tagged with ruthenium. Both antibodies are monoclonal	Same antibodies and same epitopes
Traceability	The Elecsys proBNP II assay has been standardized against the Elecsys proBNP assay (k022516). This in turn was standardized against reference standards by weighing pure synthetic NT-proBNP (1-76 amino acids) into equine serum matrix.	Same
Calibrator	Elecsys proBNP II CalSet (k072437)	Elecsys proBNP II STAT CalSet will have a different material number to avoid confusion on instrument use. The stability, value assignment and matrix will be identical.

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Immunoassay Comparison		
Feature	**Predicate Device: Elecsys proBNP II Assay (K072437) (18 Minute)**	**Elecsys proBNP II STAT Assay**
General Assay Features		
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: MODULAR ANALYTICS E170, Elecsys 2010 and **cobas e** analyzers: • After 1 month (28 days) when using the same reagent lot • After 7 days (when using the same reagent kit on the analyzer) Elecsys 1010 analyzer: • With every reagent kit • After 7 days (ambient temperature 20-25 °C) • After 3 days (ambient temperature 25-32 °C)	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: **cobas e 601**: • After 1 month (28 days) when using the same reagent lot • After 7 days (when using the same reagent kit on the analyzer)
Controls	Elecsys PreciControl Cardiac II (k072437)	Same

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Immunoassay Comparison		
Feature	**Predicate Device: Elecsys proBNP II Assay (K072437) (18 Minute)**	**Elecsys proBNP II STAT Assay**
General assay features		
Traceability / Standardization	This method has been standardized against the Elecsys proBNP assay. This in turn was standardized against reference standards by weighing pure synthetic NT-proBNP (1-76) into an equine serum matrix.	Same
Reagent Stability/ Storage	Store at 2-8 °C. Store the Elecsys proBNP II reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use. Stability: Unopened at 2-8 °C—up to the stated expiration date After opening at 2-8 °C—12 weeks On MODULAR ANALYTICS E170 and **cobas e** 601—8 weeks On Elecsys2010 and **cobas e** 411—8 weeks	Same, but only reported on the **cobas e** 601.

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Premarket Notification, 510(k) for Elecsys proBNP II STAT Assay, Continued

Immunoassay Comparison		
Feature	**Predicate Device: Elecsys proBNP II Assay (K072437) (18 Minute)**	**Elecsys proBNP II STAT Assay**
Labeled Performance Characteristics		
Measuring Range	5-35,000 pg/mL	Same
Precision	*Elecsys 1010/2010 and cobas e411 analyzers* Within-run (Repeatability) 4.2% CV @ 44.0 pg/mL 2.4% CV @ 126.0 pg/mL 1.3% CV @ 2410.0pg/mL 2.7% CV @ 33606.0 pg/mL 2.6% CV @ 82.0 pg/mL 1.2% CV @ 2318.0 pg/mL Total (Intermediate) 4.6% CV @ 44.0 pg/mL 2.6% CV @ 126.0 pg/mL 1.8% CV @ 2410.0pg/mL 3.8% CV @ 33606.0 pg/mL 2.8% CV @ 82.0 pg/mL 1.6% CV @ 2318.0 pg/mL *MODULAR ANALYTICS E170 and cobas e601:* Within-run (Repeatability) 1.9% CV @ 64.0 pg/mL 1.5% CV @ 124.0 pg/mL 1.3% CV @ 14142.0 pg/mL 1.8% CV @ 77.0 pg/mL 1.2% CV @ 2105.0 pg/mL Total (Intermediate) 3.1% CV @ 46.0 pg/mL 2.7% CV @ 125.0 pg/mL 2.7% CV @ 32805.0 pg/mL 2.7% CV @ 77.0 pg/mL 2.7% CV @ 2170.0 pg/mL	*cobas e 601:* Within-run (Repeatability) 2.4% CV @ 130.0 pg/mL 2.2% CV @ 4942.0 pg/mL 3.5% CV @ 59.0 pg/mL 2.0% CV @ 142.0 pg/mL 1.8% CV @ 522.0 pg/mL 1.9% CV @ 934.5 pg/mL 2.0% CV @ 6552.0 pg/mL 2.9% CV @ 30,870.0 pg/mL Total (Intermediate) 2.5% CV @ 130.0 pg/mL 2.6% CV @ 4942.0 pg/mL 3.5% CV @ 59.0 pg/mL 2.5% CV @ 142.0 pg/mL 2.0% CV @ 522.0 pg/mL 2.5% CV @ 934.5 pg/mL 2.3% CV @ 6552.0 pg/mL 5.4% CV @ 30,870.0 pg/mL

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Immunoassay Comparison		
Feature	**Predicate Device: Elecsys proBNP II Assay (K072437) (18 Minute)**	**Elecsys proBNP II STAT Assay**
Labeled Performance Characteristics		
Analytical Sensitivity	Limit of Blank (LoB) not reported Limit of Detection (LoD) 5.00 pg/mL Limit of Quantitation (LoQ) Functional Sensitivity: 50.00 pg/mL	Limit of Blank (LoB): 5.00 pg/mL Limit of Detection (LoD): 5.00 pg/mL Limit of Quantitation (LoQ) Functional Sensitivity: 50.00 pg/mL
Hook Effect	There is no high-dose hook effect at proBNP concentrations up to 300,000 pg/mL (300 ng/mL).	Same
Limitations	The assay is unaffected by: • Hemoglobin ≤ 0.1 g/dL • Bilirubin up ≤ 25 mg/dL • Triglycerides ≤ 1,500 mg/dL • Biotin ≤ 30 ng/mL • Rheumatoid factors ≤ 1,500 IU/mL • In vitro tests were performed on 51 commonly used pharmaceuticals. No interference with the assay was found. • The risk of interference from potential immunological interactions between test components and rare sera has been minimized by the inclusion of suitable additives. • As with all tests containing monoclonal mouse antibodies, erroneous findings may be obtained from samples taken from patients who have been treated with monoclonal mouse antibodies or have received them for diagnostic purposes. • In rare cases, interference due to extremely high titers of antibodies to streptavidin and ruthenium can occur. The test contains additives which minimize these effects. • For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.	Same

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<table>
<tr><th colspan="3">Immunoassay Comparison</th></tr>
<tr><th>Feature</th><th>Predicate Device: Elecsys proBNP II Assay (K072437) (18 Minute)</th><th>Elecsys proBNP II STAT Assay</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Method Comparison</td><td colspan="2">Both assays run on the cobas e 601
<table>
<tr><td>n = 120
Min = 5.10 pg/mL
Max = 30,583 pg/mL</td><td>Passing/Bablok</td><td>Linear Regression</td><td>Deming Regression</td></tr>
<tr><td>Slope</td><td>0.992</td><td>0.986</td><td>0.988</td></tr>
<tr><td>Intercept</td><td>-2.141</td><td>13.964</td><td>8.83</td></tr>
<tr><td>Tau/r/rho</td><td>0.987</td><td>0.998</td><td>1.00</td></tr>
</table></td></tr>
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Premarket Notification, 510(k) for Elecsys proBNP II STAT Assay CalSet

CalSet Comparison		
Feature	**Predicate Device: Elecsys proBNP II CalSet (K072437)**	**Elecsys proBNP II STAT CalSet**
Labeled Performance Characteristics		
Intended Use	Elecsys proBNP II CalSet is used for calibrating the quantitative Elecsys proBNP II assay on Elecsys and **cobas e** immunoassay analyzers.	Elecsys proBNP II STAT CalSet is used for calibrating the quantitative Elecsys proBNP II STAT assay on the **cobas e** 601 immunoassay analyzer.
Levels	Two	Same
Format	Lyophilized equine serum	Same
Analyte Concentration	Cal 1: ~140 pg/mL Cal 2: ~ 2,700 pg/mL	Same
Handling	Dissolve carefully the contents of one bottle by adding exactly 1.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully avoiding the formation of foam. Transfer the reconstituted calibrator into the empty, labeled snap-cap bottles supplied.	Same
Stability	Unopened: • Store at 2 – 8°C until expiration date. Reconstituted: • 2 – 8°C: 2 weeks • -20°C: 3 months (freeze only once) • On Elecsys 1010/2010 and cobas e411 analyzers at 20 – 25°C: up to 5 hours • On MODULAR ANALYTICS E170 and cobas e601 analyzers: use only once	Unopened: • Store at 2 – 8°C until expiration date. Reconstituted: • 2 – 8°C: 2 weeks • -20°C: 3 months (freeze only once) • On the analyzer: use only once

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Confidentiality

Roche Diagnostics Corporation requests that the FDA not disclose the nature or existence of the premarket notification until the substantial equivalence decision has been reached.

Closing

We trust that the information provided in this Premarket Notification [Special 510(k)] will support a determination of substantial equivalence for the Elecsys proBNP II STAT Immunoassay.

If you should have questions or require further information, please do not hesitate to contact me.

- Phone: (317) 521-3338
- FAX: (317) 521-2324
- jane.phillips@roche.com

Sincerely,

Jane Phillips, PhD
Regulatory Affairs Principal
US Regulatory Submissions
Roche Diagnostics Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

FEB - 4 2010

Roche Diagnostics Corp.
c/o Dr. Jane Phillips, Regulatory Affairs Principal
9115 Hague Road
Indianapolis, IN 46250

Re: k092649
Trade Name: Elecsys proBNP II STAT Immunoassay, Elecsys proBNP II STAT CalSet
Regulation Number: 21 CFR §862.1117
Regulation Name: B-type Natriuretic Peptide Test System
Regulatory Class: Class II
Product Codes: NBC, JIT
Dated: January 4, 2010
Received: January 5, 2010

Dear Dr. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k092649

Device Name: Elecsys proBNP II STAT Immunoassay

Immunoassay for the in vitro quantitative determination of N-terminal pro-brain natriuretic peptide in human serum and plasma. The Elecsys proBNP II STAT assay is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure. The test may also serve as an aid in the assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the **cobas** e 601 immunoassay analyzer.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092649

Indications for Use Form

510(k) Number (if known): k092649

Device Name: Elecsys proBNP II STAT CalSet

Elecsys proBNP II STAT CalSet is used for calibrating the quantitative Elecsys proBNP II STAT assay on the **cobas e** 601 immunoassay analyzer.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092649